

REMARKS

I. Status of the Claims

While neither agreeing nor disagreeing with the Examiner's rejections, solely to expedite prosecution of this application, claim 1 has been amended to incorporate the language of claim 2. Claim 2 has now been cancelled. Claims 5 and 10 have been amended. Support for the amendments to the claims can be found in the claims as originally filed and throughout the specification. No new matter has been added by the present amendment. Upon entry of this amendment, claims 1 and 3-10 will be pending.

II. Objection to the Specification

The abstract of the disclosure is objected to because it is a single sentence fragment and does not comprise a complete sentence. This objection has been rendered moot by the present amendment. Applicants respectfully request this rejection be withdrawn.

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Claims 1-10 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 1-2, 5, 7-8 and 10 stand rejected. Applicants respectfully traverse this rejection.

With respect to claims 1-2, and 7-8, the term "adequate" does not render the claims indefinite as it is part of the term "duration of adequate immune memory" which is defined in on page 7, lines 11-13 of the Specification. Applicants respectfully request that this rejection be withdrawn.

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III. First Rejection Under 35 U.S.C. § 102(b)

Claims 1, 3-4 and 6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Olson et al., Am. J. Vet. Res. Sept. 1988, Vol 49, no. 9, pages 1460-1466 ("Olson"). This rejection has been rendered moot by the amendment of claim 1 to include the language of

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Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Volti et al., *Eur. J. Epidem.* (1995), Vol. 11, pages 217-219 (“Volti”). This rejection has been rendered moot by the amendment of claim 1 to include the language of non-rejected claim 2 as set forth above. Regardless, Volti would not anticipate Applicants’ claimed invention since it is directed to the study of humans and not to animals. Since Volti fails to teach or suggest a recited claim element, Volti would neither anticipate nor render obvious Applicants’ claimed invention. Applicants respectfully request this rejection be withdrawn.

V. Rejection Under 35 U.S.C. § 102(a)

Claim 1 stands rejected under 35 U.S.C. § 102(a) as being anticipated by Yang et al., *J. Epidem.*, (Aug. 1999), Vol. 9, No. 4, pages 209-215 (“Yang”). This rejection has been rendered moot by the amendment of claim 1 to include the language of non-rejected claim 2 as set forth above. Regardless, Yang would not anticipate Applicants’ claimed invention since it is directed to the study of humans and not to animals. Since Yang fails to teach or suggest a recited claim element, Yang would neither anticipate or render obvious Applicants’ claimed invention. Applicants respectfully request this rejection be withdrawn.

VI. First Rejection Under 35 U.S.C. § 103(a)

Claims 1-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Olson et al., *Am. J. Vet. Res.* Sept. 1988, Vol 49, no. 9, pages 1460-1466 (“Olson”), in view of Simonsen et al., *Vaccine*, (1987), Vol.5, no. 2, pp. 115-122 (“Simonsen”) and Dodds, US Patent No. 6,287,254 (“Dodds”). Applicants respectfully traverse this rejection.

Applicants contend that the present invention is not *prima facie* obvious in view of the cited references. The Board of Patent Appeals and Interferences has stated that “to establish a *prima facie* case of obviousness, it is necessary for the examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the

applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention.” Ex parte Levengood, 28 USPQ2d 1300, 1301 (BOPAI 1993). Not only must there be evidence of motivation, but also the skilled worker must have an expectation that the combination of teachings would be successful.

Here, none of the references alone or in combination provide the requisite teaching or suggestion to modify their teachings and arrive at Applicants’ claimed invention with any reasonable expectation of success. Specifically none of the references teach or suggest the use of a duration of adequate immune memory estimation equation derived by a logistic regression analysis of the first and the second indicators and the vaccine administration record. The Examiner has recognized this deficiency in Olson. Office Action, page 8, lines 1-3. As stated above, Simonsen is directed to the study of humans and is silent as to animals and thus would not remedy any of the deficiencies of Olson. Dodds also fails to remedy the deficiencies of Olson since it also does not teach or suggest the derivation of an adequate immune memory estimation equation from logistic regression analysis of the first and second indicators and the vaccine administration record for determining a duration of adequate immune memory, as claimed. Applicants’ claimed invention is not obvious in view of the cited references. Applicants respectfully request this rejection be withdrawn.

VII. Second Rejection Under 35 U.S.C. § 103(a)

Claims 1, 5 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Simonsen et al., *Vaccine*, (1987), Vol.5, no. 2, pp. 115-122 (“Simonsen”). This rejection has been rendered moot by the amendment of claim 1, and hence dependent claims 5 and 10, to include the language of non-rejected claim 2 as set forth above. Regardless, Simonsen would not render Applicants’ claimed invention obvious as it is directed to the study of humans and not to animals as in Applicants’ claimed invention. Since Simonsen is silent as to animals, Simonsen would not provide the requisite teaching or suggestion to modify its teachings and arrive at Applicants’ claimed invention with any expectation of success. Applicants respectfully request this rejection be withdrawn.

VIII. Conclusion

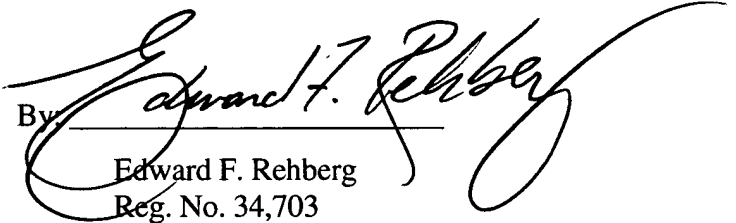
Applicants respectfully request reconsideration of the subject application in view of the above amendments and remarks. The subject application is now in condition for allowance and early notice to that effect is respectfully solicited.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 16-1445. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

Dated: March 18, 2004

By


Edward F. Rehberg
Reg. No. 34,703



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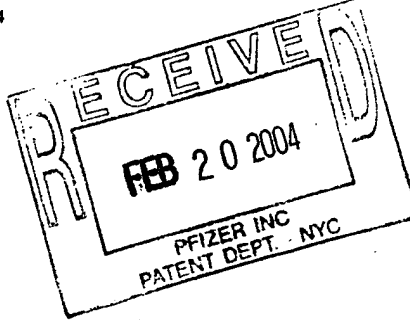
PHARMACIA

APPLICATION NO.	FILING DATE	GLOBAL INTERVENTION	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,093	02/19/2001	Michael J. Coyne	PC10751A	3040

7590

02/18/2004

Paul H. Ginsburg
Pfizer Inc
20th Floor
235 East 42nd Street
New York, NY 10017-5755



EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

RESPONSE DUE March 18, 2004**URGENT**

(Kalamazoo)
TAW
↑



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER
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20040212

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

The reply filed on 1/28/04 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): the amendment to the claims does not comply with 37 CFR 1.121 (c), which requires that the full text of all pending claims be presented. See 68 Fed. Reg. 38616. Also, see 37 CFR 1.111. Since the above-mentioned reply appears to be bona fide, applicant is given ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. This shortened statutory period for reply supersedes the time period set in the prior Office action. This time period may be extended pursuant to 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit: 1631



PATENT

Attorney Docket No. PC10751A

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Hon. Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on this 26th day of January, 2004.

By

(Signature of person mailing)

Kelly A. Smith

(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Michael J. Coyne, *et al*

Serial No.: 09/838,093

Filed: April 19, 2001

For: METHOD OF MEASURING THE
DURATION OF ADEQUATE
IMMUNE MEMORY IN
COMPANION ANIMALS

Group Art Unit: 1645

Examiner: Marjorie A Moran

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE

In response to the non-final Office Action mailed on July 24, 2003, Applicants respectfully request reconsideration of the subject application in view of the following amendments and remarks. A petition and fee for a three-month extension of time accompanies this response.

RECORDABLE

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AMENDMENT TO THE SPECIFICATION

Please replace the abstract found on page 40, lines 4-7 with the following:

A method to measure the duration of adequate immune memory for animal vaccines involving a retrospective analysis utilizing veterinary vaccine administration histories and clinical histories, and markers of immunity of animals in the field to derive a vaccine's duration of adequate immune memory is described.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (currently amended): A method of determining a duration of adequate immune memory induced by a vaccine for a disease in an animal, the method comprising:

- (a) selecting a plurality of study animals from one or more clinics, where each animal has been vaccinated with the vaccine and where a time since a last vaccination date is at least about one year and the animal has been living in a field environment for at least about one year after the last vaccination date and each animal has a vaccine administration record;
- (b) assigning each animal an indicator of immune memory, such that each animal that does not have a marker of immunity is assigned a first indicator and each animal that has the marker of immunity is assigned a second indicator; and
- (c) determining the duration of adequate immune memory from: (i) the first indicator and the second indicator; and (ii) the vaccine administration record;

wherein the duration of adequate immune memory is determined from a duration of adequate immune memory estimation equation, said duration of adequate immune memory estimation equation derived by a logistic regression analysis of the first and the second indicators and the vaccine administration record.

Claim 2 (canceled).

Claims 3-4 (original).

Claim 5 (currently amended): The method of claim 1, wherein assigning each animal the indicator of immune memory comprises:

- (a) evaluating a blood serum sample from each animal that has not shown clinical signs of the disease since the last vaccination date to detect an adequate antibody titer of at least about 2 for the disease;
- (b) administering a booster dose of the vaccine to each animal that does not display the adequate antibody titer;

- (c) evaluating a blood serum sample from each animal that has received the booster dose 3 days to 28 days following the booster dose to detect an adequate anamnestic response of at least about a 4-fold increase in serum antibody titer; and
- (d) assigning the first indicator to each animal that displayed clinical signs of the disease since the last vaccination date or that neither displays the adequate antibody titer nor displays the adequate anamnestic response and assigning the second indicator to each animal that displays either the adequate antibody titer or the ~~sufficient~~ adequate anamnestic response.

Claims 6-9 (original)

Claim 10 (currently amended): The method of claim 1, which further comprises:

- a) assigning each animal that has displayed clinical signs of the disease since the last vaccination or that neither displays a cellular immune response, nor an adequate antibody titer of at least about 2 for the disease, nor an adequate cellular titer nor an adequate anamnestic response of at least about a 4-fold increase in serum antibody titer the first indicator;
- b) designating each animal which is not assigned the first indicator as either a high risk animal or a low risk animal;
- c) assigning each low risk animal that displays either a cellular immune response or that displays either the adequate antibody titer or the ~~sufficient~~ adequate anamnestic response the second indicator;
- d) assigning each high risk animal that has no history of the disease in question and where there is evidence of prevalence of the disease in question in the region the second indicator; and
- e) assigning each high risk animal that has no history of the disease in question that displays either the cellular immune response, or the adequate antibody titer or the ~~sufficient~~ adequate anamnestic response, the second indicator.

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Respectfully submitted,

Dated: January 26, 2004

By: Christine S. Lee

Christine S. Lee
Reg. No. 42,788

Pfizer Inc.
Patent Department, MS 8260-1611
Eastern Point Road
Groton, Connecticut 06340
(860) 686-2144